Message

From: McNamara, Katelan (Katie) [McNamara.Katelan@epa.gov]
Sent: 4/23/2021 12:51:20 PM
To: Sheehan, Eileen [Sheehan.Eileen@epa.gov]
CC: Kramek, Niva [kramek.niva@epa.gov]; Parsons, Doug [Parsons.Douglas@epa.gov]; Wolf, Joel [Wolf.Joel@epa.gov]; Ellenbogen, Victoria [Ellenbogen.Victoria@epa.gov]; Wheeler, Cindy [Wheeler.Cindy@epa.gov]
Subject: Earthjustice and TCE
Attachments: Transcript_TCE_Public Webinar_12.15.2020.pdf; 2021-04-05_EarthJustice_TSCA Risk Management Roadmap.pdf; Environmentalist Letter on Science Integrity_TCE_2.26.21.pdf

Eileen –

This is what we can work with! See the insideepa article below. I attached the Earthjustice letter mentioned below. They had a public comment at my webinar, if you search Earthjustice in the transcript attached. AND Earthjustice submitted an overarching letter on how to carry out the risk management for the first 10. I will need time to read through, so can we meet at 10? ☺

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From: Euling, Susan <Euling.Susan@epa.gov>
Sent: Thursday, March 18, 2021 9:41 AM
To: McNamara, Katelan (Katie) <McNamara.Katelan@epa.gov>
Subject: Inside EPA article on TCE

Have you seen this?
https://insideepa.com/tsca-news/acc-seeks-new-review-tce-data-epa-weighs-reopening-evaluation

ACC Seeks New Review Of TCE Data As EPA Weighs Reopening Evaluation

March 17, 2021

Chemical manufacturers say that if EPA grants environmentalists' requests to reconsider the Trump administration's evaluation of trichloroethylene (TCE), it should convene a panel of independent experts to review research on in utero health effects that critics say the agency improperly discarded, rather than simply reversing that decision.

The American Chemistry Council (ACC) writes in a March 16 letter to acting EPA toxics chief Michal Freedhoff that while it disagrees with environmentalists' claims that the agency should have included a controversial study linking TCE to fetal cardiac malformations in the evaluation, if the Biden administration takes up the request it should trigger a fresh scientific review.

ACC writes that "recent reviews by the Agency's Science Advisory Committee on Chemicals (SACC) and the National Academies of Science, Engineering and Medicine (NASEM) have confirmed that the weight of scientific evidence does not support the use [of] the cardiac endpoint as a basis for risk determination. If your office decides to reconsider the conclusions regarding cardiac effects, however, we urge you to commission an independent review panel with the appropriate expertise to ensure the transparency and objectivity of the process."

ACC Senior Director Stephen Risotto tells *Inside TSCA* that the group's message to EPA is, "If you are going to look at this endpoint -- we're not advocating that [you do] -- but if you are, you need to do it with an independent panel" of experts.

Environmentalists have urged EPA to revisit a host of Trump-era Toxic Substances Control Act (TSCA) actions including many or all of the 10 existing-chemical evaluations it completed. On TCE, that request came through a Feb. 26 letter to then-Acting Administrator Jane Nishida, signed by seven environmental groups.

The writers argued that the Trump EPA's decision to base the TCE evaluation on immune system harms rather than fetal heart damage -- a top criticism of the evaluation -- was the product of top political officials overruling career staff.

EPA analyzed the fetal cardiac data, and made that analysis part of the final evaluation, but chose not to use it as a basis for quantitative conclusions on risks posed by TCE -- a move the environmental groups say constitutes "political interference" in the scientific process.

After EPA published the final evaluation last fall, ACC released a statement criticizing EPA for not going "far enough in invalidating" the fetal cardiac endpoint and specifically the controversial study known as Johnson et al, in the final document.
In its new letter, ACC argues that the environmentalists have not responded to criticism of EPA's analysis, from both the SACC committee that peer-reviewed the draft evaluation and, more recently, a National Academy of Sciences (NAS) panel that found serious flaws in the systematic review approach the Trump administration used to craft all 10 of its TSCA chemical evaluations.

SACC's peer review report, released last June, revealed that science advisors were unable to agree on whether the agency appropriately chose to base its analysis of TCE risks on the chemical's adverse immune system effects rather than its historical -- and more conservative -- focus on fetal heart defects. The report urged the agency to better justify its decision to decline to use the study while also questioning the immunotoxicity study EPA used instead.
ACC's letter also notes that the NASEM report on EPA's use of systematic review criticizes the agency's evaluation of the TCE fetal cardiac studies specifically, along with critiquing the overall systematic review approach that officials have since pledged to replace.

It says that NAS report "concluded that overall confidence in the results of the TCE hazard review was 'critically low' and that the review 'should not be relied on to provide an accurate and comprehensive summary of the available studies.'"

'Latest And Greatest' Research
Industry groups have long questioned the validity of the Johnson study, conducted by academic researchers at the University of Arizona years ago, arguing that its unusual study design compromises it so that it cannot be used for risk evaluation.

Trade groups such as the Halogenated Solvents Industry Alliance have sought to repeat the study and have been unable to replicate its results, leaving them to further question its findings. Critics, however, question the approaches industry has used to conduct these replication efforts.

EPA's research office debated the issue for years before finalizing in 2011 an Integrated Risk Information System (IRIS) assessment that used the fetal cardiac malformations for its risk estimate calculations, resulting in a strict number that drove stringent and controversial guidances from some of EPA's regional offices regarding how to respond to TCE vapor intrusion from contaminated sites.

But Risotto says the TSCA program should not be bound by those decisions.

"Our view is the TSCA risk evaluations should be the latest and greatest; they should replace or supplement what's in the IRIS values," Risotto says of future EPA rules on TCE or other risk management actions. He adds that EPA "shouldn't be working with an assessment that's 10 years old."

Risotto noted that several years ago, when EPA selected TCE as one of the first 10 chemicals that EPA would assess in the TSCA program, "we approached [EPA's] Superfund office . . . all the vapor intrusion [guidance] is their territory, and said, 'There's a new evaluation [coming] that should supplant the IRIS assessment. You should withdraw what you've been saying' with the hope that the [TSCA] risk evaluation would support our view that the cardiac endpoint should not be used. [The waste office] said let's wait and see what the TSCA office does. We're still in that mode."

He continues that the SACC and NAS critiques of the fetal cardiac study shows the need for, at least, further review before it could inform TSCA action -- and that environmentalists' arguments that the panels lacked expertise on developmental toxicology are beside the point.

Risotto said that while he agrees there were no developmental toxicology experts among the SACC panelists, the problems with the fetal cardiac endpoint and the Johnson study's design were such that you "don't have to get to developmental toxicology to see why it shouldn't be used. . . . Anybody who does studies and risk assessment would raise concerns."

However, he agreed that "from a matter of transparency and completeness it would make sense" for the review panel ACC has proposed to include scientists with that expertise. -- *Maria Hegstad* (mhegstad@iwpnews.com)

Sue

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